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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/462,094 | 01/11/2000 | PETER K.T. PANG | P8061-9012 | 4670 |

6449 7590 10/16/2003

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EXAMINER

BORIN, MICHAEL L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1631

18

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,094

Applicant(s)

Pang et al

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/11/03
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-20 is/are pending in the application.
- 4a) Of the above, claim(s) 3-6, 9-14, and 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7, 8, 15, 19, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/11/2003 has been entered.

Status of Claims

1. Claim 1 is canceled. Claims 7,8,15,19 are amended. Claims 3-20 are pending. Claims 3-6,9-14,16-18 remain withdrawn from consideration, as being drawn to a non-elected groups. Claims 7,8,15,19,20 are under consideration.

Claim Rejections - 35 USC § 102 and 103.

5. Claims 7,15,19,20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Schinitzky (US Patent 4,473,551).

Instant claims 1,7 are drawn to shark cartilage extract and pharmaceutical composition comprising thereof.

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The reference describes preparation of shark cartilage extract by extraction of shark cartilage with water at 5°C and separating supernatant by centrifugation, and lyophilizing the purified extract. See col. 2, lines 35-45, and col. 3, lines 42-60. Pharmaceutical compositions comprising the shark cartilage extract are used for treatment of inflammation. See columns 4,5.

The instantly claimed product is in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need to be established and not that of the recited process steps. In re Brown, 173 USPQ 685 (CCPA 1972); In re Wertheim, USPQ (CCPA 1976). Since the Office does not have the facilities for examining and comparing applicants' extract with the extract disclosed in the prior art, the burden is on applicant to show novel or unobvious difference between the claimed product and the product of the prior art. There is no distinguishing characteristics claimed for the extract; therefore the claimed and referenced extracts are presumed to have same activities. As for the claimed anti-PTH activity of the extract, it has been held that where applicant claims a composition in terms of function, property or characteristic where said function is not explicitly shown by the reference and where the examiner has explained why the function, property or characteristic is considered inherent in the prior art, it is appropriate for the examiner to make a rejection under both the applicable section of 35 USC 102 and 35 USC 103 such that the burden is placed upon the applicant to provide clear

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evidence that the respective compositions do in fact differ. Since the Office does not have the facilities for examining and comparing applicants' extract with the extract disclosed in the prior art, the burden is on applicant to show novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.d. 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

In regard to claim 15 providing percentile content of the components in the extract, the reference does not recite the content of components in the extract. Again, since the Office does not have the facilities for examining and comparing applicants' extract with the similarly prepared extract disclosed in the prior art, the burden is on applicant to show novel or unobvious difference between the claimed product and the product of the prior art. Further, it would be a matter of routine experimentation to select optimal concentration ranges of components of a cartilage composition.

7. Claim 8 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Schinitzky (US Patent 4,473,551) for the reasons set forth above for claims 7,15,19,20, and further as evidenced by Echard et al. (Database Medline, DN 21572448, Mol. Cell. Biochem., 2001, vol. 225, 85-91).

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The reference is applied as discussed above. Further, the composition described in the reference also contains glucosamine (see col. 4) which, as evidenced by the abstract of Echard, lowers blood pressure, and hence is considered as anti-hypertensive agent.

Conclusion.

9. No claims are allowed

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

October 9, 2003

mlb

